

*Research Article***Laparoscopic Cholecystectomy Using Harmonic Scalpel Versus Conventional Laparoscopic Cholecystectomy****Amer Yehia (MD), Esam Mahmoud (MD), Mohammed El-Dsouky**

Department of General Surgery, Faculty of medicine Al-Azhar University (Assuit)

Abstract

Background: laparoscopic cholecystectomy is the worldwide gold standard treatment of symptomatic gallbladder lithiasis. During the conventional LC, we used usually clips for closure of cystic duct and artery and dissector, electro-surgical hook, spatula and/or scissor for dissection of cystic duct and artery and sealing of gall bladder from liver bed. Now, single instrument called harmonic scalpel is introduced as a potential replacement for all of these instruments. **Objective:** To evaluate the safety, efficacy and clinical outcome of LC using harmonic scalpel compared with conventional LC. **Patients and Methods:** Our prospective randomized study was carried out during the period from February 2018 to August 2018 at Azhar Assuit University Hospital, and included 60 adult patients presented with chronic calculous cholecystitis divided randomly into 2 groups. All patients of both groups were signed the informed consent and assessed preoperative (history, clinical examination, CBC, LFTs, RFTs, virology and Pelvi-abdominal ultrasound), intraoperative (time, incidence of gall bladder perforation, bleeding and conversion to open procedure) and postoperative (pain, analgesia, drain, bile leakage, hospital stay and wound infection). **Results:** No statistically significant difference was found age, sex, BMI and associated diseases between both groups but there is significant difference in operative time, incidence of gall bladder perforation, blood loss, postoperative pain, drain and hospital stay. No significant difference in wound infection. No incidence of bile leakage or conversion to open procedure in both groups. **Conclusion:** Harmonic scalpel in general is an efficient tool for complete hemobiliary sealing with high safety profile.

Keywords: Harmonic scalpel, laparoscopic cholecystectomy**Introduction**

Laparoscopic cholecystectomy is the worldwide gold standard treatment of symptomatic gallbladder lithiasis. The technique of traditional laparoscopic cholecystectomy still has areas of modifications, including complications of clips being got out. The use of harmonic scalpel for tissue cutting and coagulation is a potential replacement for electro-cautery, which related to different complications. The harmonic scalpel has been used safely in other general surgical operations. The primary use of the harmonic scalpel in laparoscopic cholecyst-ectomy was for the division of the cystic artery. Now, Blade tip provide for the reliable ultrasonic division and closure of the cystic duct.

The standard laparoscopic cholecystectomy is usually performed using a electro-surgical hook

for dissection and clips for closure of the cystic duct and artery. Other techniques for duct ligation have included linear stapler, endoloops or sutures which are however, seldom used^(1,2).

Although we consider laparoscopic cholecyst-ectomy safe technique, some dangers are associated as the high risk of thermal injuries with the use of the mono-polar electro-surgery, visceral and solid organ injuries due to frequent exchange of instruments and bile leakage due to slippage of the clips⁽³⁾.

Designed as a safe alternative to electro-cautery for the hemostatic dissection of tissue, harmonic scalpel was introduced into clinical use nearly a decade ago⁽⁴⁾.

This innovative method of cutting tissue was based on the cavitation and coagulating effects provided by a rapidly vibrating blade when in contact with various tissues⁽⁵⁾. The resulting decrease in temperature, smoke, and lateral tissue damage placed the harmonic scalpel in contrast to the effects seen with the more traditional electrocautery.

Furthermore, total harmonic scalpel dissection in the performance of a laparoscopic cholecystectomy is a technique described only in the European literature⁽⁶⁾ and, at best, is only anecdotal in the United States.

Harmonic scalpel is a piece of medical equipment used in surgical procedures which uses ultrasound technology to cut tissues while simultaneously sealing them the edges of the cut. This system is composed of a hand-held ultrasonic transducer, generator, hand switch, scalpel that serves as the cutting instrument and foot pedal. The scalpel vibrates about 55,500 Hertz while cutting through a tissue and sealing them at the same time by employing protein denaturation to stop bleeding. The ultrasonically activated scalpel (Harmonic-Ethicon Endo Surgery INC - Johnson & Johnson Medical SPA Somerville, NJ) was introduced into clinical use more than a decade ago.

Its technology depends on the application of ultrasound within the harmonic frequency range to tissues and allows 3 effects that act synergistically: Coagulation, cutting and cavitation⁽⁷⁾. The temperature obtained and the lateral energy spread are lower than those detected when the mono-polar hook is used, thus reducing the risk of tissue damage⁽⁸⁾.

The harmonic scalpel also considered an effective tool as certified by the FDA in 2006 for closure of biliary ducts and vessels whose diameter is ≤ 5 mm.

Several studies have demonstrated the safety, efficacy of the use of the harmonic scalpel for dissection of the gallbladder, but only a few researchers have examined its effectiveness in the closure of the cystic artery and duct. In 1999, the use of ultrasonically activated shears

was reported for the first time for dissection, division and closure of the cystic duct and artery⁽⁹⁾.

Moreover, the use of a single instrument during the whole procedure decreases the risk of distant organ injuries⁽¹⁰⁾. The replacement of scissors, dissectors and clips by harmonic scalpel gives the opportunity to use a single procedure limiting the number of the instruments and consequently, reducing the possibility of causing injuries to intraabdominal organs⁽¹¹⁾.

Besides being equally safe, advantages to clipless laparoscopic cholecystectomy by harmonic shears versus conventional laparoscopic cholecystectomy is a shorter operative time, less incidence of gallbladder perforation, less rate of conversion to open cholecystectomy and less post-operative pain⁽¹²⁾.

Aim of the Work

To evaluate the safety, efficacy and clinical outcome of laparoscopic cholecystectomy using harmonic scalpel compared with conventional laparoscopic cholecystectomy.

Patients and Methods

This is a prospective randomized study that was carried out during the period from February 2018 to August 2018 at Azhar Assuit University Hospital, and included 60 adult patients, 46 females and 14 males with a mean age 38.86 years presented with chronic calculous cholecystitis divided randomly into 2 groups: **Group A:** Included 30 patients who underwent conventional laparoscopic cholecystectomy with closure of cystic duct and artery by titanium clips, division of structures by laparoscopic scissors and dissection of gallbladder by electro-cautery hook. **Group B:** Included 30 patients who underwent laparoscopic cholecystectomy using harmonic scalpel (Ethicon Endo-Surgery) for closure and division of cystic duct, artery and for dissection of gall bladder.

This study **included** patients within age 18-60 years presenting with chronic calculous cholecystitis and **excluded** patients above 60 years or below 18 years or with history of upper

laparotomy or with acute cholecystitis or with common bile duct stones or with chronic liver diseases and pregnant women. All patients of both groups were signed the informed consent and subjected to the following: **Pre-operative assessment:** by taking full history (especially symptoms of gallstone diseases), clinical examination (focusing on manifestation of gallstone diseases) and the following investigations: CBC, liver function tests (serum albumin, SGOT, SGPT, total and direct bilirubin, alkaline phosphatase and PT), renal function tests (urea, creatinine), HCV and HBV markers and pelvi-abdominal ultrasound. Then, patients were randomly divided into two groups using closed envelopes, group A (conventional) & group B (Harmonic).

All patients were subjected to the **intra-operative assessment of Time** (was measured from the insertion of last port to delivery of the gallbladder), **incidence of gall bladder**

perforation, sealing and closure of cystic duct and artery, blood loss and conversion to open procedure.

The patients started oral feeding 8h post-operatively and **the following parameters were assessed postoperatively** at the period of hospital stay: **Pain:** was evaluated at 12h, 24h and 48 hours after operation using a Numeric Pain scoring system:

Rating	Pain Level
0	No pain
1-3	Mild Pain (nagging, annoying, interfering little with ADLs)
4-6	Moderate Pain (interferes significantly with ADLs)
7-10	Severe Pain (disabling; unable to perform ADLs)

The Numeric Rating Scale (NRS-11) is an 11–point scale for patient self-reporting of pain. It is for adults and children 10 years old or older.⁽¹³⁾

Analgesia: in the form of non-steroidal anti-inflammatory drug was administered intramuscularly when required, **drain** (content [serosanguinous, bile, pure blood] and amount [considered nil if less than 50 cc] was observed). Drain usually removed before discharge of patients), **bile leakage** (drain and pelvi-abdominal ultrasound), **hospital stay, wound infection and associated morbidity.**

Patients were discharged once clinically free and tolerating oral feeding. Drain was removed before discharge and patients visit us at the general

surgery clinic at the day 7 after operation then at a rate one visit per 2 weeks for 2 months as a long term follow up.

Statistical analysis

Gathered data were processed using SPSS version 15 (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as mean ± SD while qualitative data were expressed as numbers and percentages (%). Student test was used to test significance of difference for quantitative variables while Chi square was used to test significance of difference for qualitative variables. A probability values (p-value) <0.05 was considered statistically significant.

Results

Table (1): Demographic Data, associated diseases

	<i>Over all (N=60)</i>	<i>Group A (n=30)</i>	<i>Group B (n=30)</i>	<i>P value</i>
<i>Age " years "</i>				
Range	21-59	23- 59	21-58	
Mean \pmSD	38.86 \pm 12.95	38.96 \pm 13.03	38.76 \pm 13.1	(NS)
<i>Sex no. of patients (%)</i>				
Female (%)	46(76.7%)	22(73.3%)	24(80%)	0.54(NS)
Male (%)	14(23.3%)	8 (26.7%)	6 (20%)	
<i>BMI</i>				
Range	21.0-32.5	21.01- 32.5	22.23-31.7	
Mean \pmSD	26.3 \pm 2.0	26.1 \pm 2.1	26.5 \pm 1.8	0.29(NS)
D.M.	18	8 (26.66%)	10 (30%)	0.2(NS)
Hypertension	12	6(20%)	6(20%)	0.1(NS)
Bronchial Asthma	3	2(6.66%)	1(3.33%)	0.2(NS)
Ischemic Heart	3	1(3.33%)	2(6.66%)	0.2(NS)
Atherosclerosis	2	1(3.33%)	1(3.33%)	0.9(NS)

Table (2): Operative data.

	Group A	Group B	P value
Operative time			
Range	38-115	28-98	0.032(S)
Mean \pmSD	58.6 \pm 19	48.4 \pm 16.9	
Operative time without Gall bladder perforation			
Range	38-90	28-85	
Mean \pmSD	55.5 \pm 14.1	46.8 \pm 14.3	0.024(S)
Operative time with Gall bladder perforation			
Range	45-115	98	
Mean \pmSD	86.6 \pm 36.8	98	0.85(NS)
GB perforation	3(10%)	1(3.3%)	0.31(NS)
IO bleeding			
Range	60-110	30-75	<0.001(S)
Mean \pmSD	84.9 \pm 13.11	48.2 \pm 11.41	
Conversion to open	0	0	

Discussion

The Harmonic scalpel (HS) preferred traditional diathermy during surgical dissection due to less spread of heat, smokeless dissection and safety to the surgeon⁽¹⁴⁾.

Laparoscopic cholecystectomy is the gold standard treatment for gallstones. Outcomes have proved the ultrasonically activated (Harm-

onic) scalpel to be an effective and safe instrument for dissection and hemostasis in both open and laparoscopic surgical procedures. Up to the present time, the primary use of the harmonic scalpel in laparoscopic cholecystectomy has been for division of the cystic artery and dissection of the liver bed. Now, blade tip provide for the reliable ultrasonic division and closure of the cystic duct⁽³⁾.

The ultrasonic scalpel causes three effects that act synergistically: cavitation, coaptation/ coagulation and cutting. The lateral energy spread is minimal, and the risk of distant tissue damage is lower than with electrosurgery⁽¹⁵⁾.

In recent reports, rates for conversion to open procedure during laparoscopic cholecystectomy have ranged from 0% to 9%⁽¹⁶⁾. In our work, the rate of conversion was 0% in both groups; this rate is less similar to that reported by El Nakeeb et al.,⁽¹⁷⁾ who reported that, the rate of conversion to open cholecystectomy was 5% for conventional laparoscopic cholecystectomy and 3.3% for laparoscopic cholecystectomy using harmonic scalpel.

Conclusion

Based on the results of our present study, Harmonic scalpel in general is an efficient tool for complete hemo-biliary sealing with high safety profile. The use of harmonic scalpel in the laparoscopic cholecystectomy is associated with a shorter operative time, lower incidence of gallbladder perforation, less rate of conversion to open cholecystectomy, lower incidence of biliary leak, less post-operative pain and analgesia and shorter hospital stay. The major merit is its relatively high cost, and limited use in mega cystic duct sizing more than 6mm.

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